

PATENT
70063-00004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho	Art Unit: 1617
Serial No.: 10/599,779	Examiner: Gina Yu
Filed: 06/28/2007	
Title: SKIN LIGHTENING METHOD	

REPLY TO EXAMINER'S ANSWER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

The appellant filed an Appeal Brief on November 1, 2010 in the above-identified application (the "Appeal Brief"), which was answered with an Examiner's Answer on March 24, 2011 (the "Answer"). This Reply To Examiner's Answer (the "Reply") is respectfully submitted in response to the Answer.

The Answer essentially repeats the reasoning set forth in the Final Office Action, which has already been opposed by appellant's Appeal Brief. This reasoning commits the reversible error of combining a reference (Herschler) with a dictionary definition, in a way that fails to even remotely comply with any recognized rationale for supporting a conclusion of obviousness as set forth in KSR v. Teleflex. The defects in the rationale supporting the conclusion of obviousness have been adequately laid out in the Appeal

Brief, and therefore this Reply primarily addresses the “Response to Arguments” section of the Answer. In addition, the Reply points out certain evidence and arguments laid out in the Appeal Brief that were ignored by the Answer.

Errors and Oversights Of The Answer

The Answer ignores or does not adequately address evidence and related arguments supporting patentability provided by the Appeal Brief, as summarized below.

Skin Tone Lightening Is An Unexpected Result

Lightening a person’s natural skin tone was a unexpected result of administering MSM. Appeal Brief, p. 10; see also p. 6-10. The entirety of the Answer’s rebuttal to this showing of the Appeal Brief relies on misconstruing the references Herschler and Salim. However, neither reference contains any hint that MSM could be used to lighten natural skin tone, and neither reference discloses any dose of MSM that would have inherently caused a lighter skin tone. In addition, the testimony of two disinterested experts is in the record and discussed in the Appeal Brief at page 10. Both experts testified that lightening of skin tone was an unexpected result of administering MSM. The Answer provides no evidence to show otherwise, and relies instead on mischaracterization of the references and the application to reach a conclusion that is wholly improper.

As noted in the Answer, the presence of unexpected results can be an indicator of non-obviousness. Pfizer Inc. v. Apotex Inc., 480 F.3d 1348, 1368-69 (Fed. Cir. 2007). The claims on appeal define a novel dosing regimen for MSM that achieves an unexpected result. Objective evidence of unexpected results may constitute the most probative and powerful evidence of nonobviousness available. Ortho-McNeil v Mylan Labs, 520 F.3d 1358 (Fed. Cir. 2008). All evidence, including evidence rebutting a

prima facie case of obviousness, must be considered when properly presented. In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007). Here, the *prima facie* case of obviousness presented against the appealed claim is clearly deficient, or at best, very weak. The objective evidence of unexpected results, in addition to the weakness of the *prima facie* case, provide a clear basis for reversal of the rejections.

The Answer finds that appellant has not presented objective evidence of unexpected results. Answer, p. 11. This is incorrect and utterly unfounded. The application itself presents the unexpected results and experimental conditions. The prior art lacks any hint that MSM can cause lightening of skin tone. Appellant has provided declarations from two independent experts, backing up the objective fact that the skin lightening results of administering MSM would have been unexpected at the time the discovery was made. What other kind of evidence is possible? None. The evidence presented should be more than sufficient to establish the presence of unexpected results.

Herschler's "Beautify The Complexion"

The Answer fails to rebut the appellant's showing that one of ordinary skill would not have received the slightest suggestion from Herschler that MSM might alter natural skin color in any way. Instead, a reader of ordinary skill would have concluded that MSM is useful for beautifying the skin by rendering it more pliable and smoother, or by reducing irritation. Appeal Brief, p. 6-8. The Appeal Brief includes detailed reasons supported by expert testimony to demonstrate why Herschler would have been understood in this way. The Answer ignores these reasons and the entire context of Herschler to essentially argue that merely because "complexion" may sometimes refer

to skin tone, it must be understood to do so in Herschler. Answer, p. 9. However, Webster's and other dictionaries offer more than one meaning for "complexion" relevant to the cosmetic arts, and the Answer does nothing to rebut the Appeal Brief's showing that Herschler uses "beautify the complexion" to refer only to the softening and smoothing effect of MSM that Herschler described, and not to any skin lightening effect.

The Appeal Brief and the testimonial evidence point out convincing reasons why Herschler clearly fails to disclose any link between MSM and skin tone. However, the Board need not rely on the appellant or her experts to conclude that one of ordinary skill would not have received the slightest suggestion that MSM might alter natural skin color from Herschler, alone or in combination with any number of dictionaries. All that is required is a good faith, unbiased reading of the reference. The appellant urges the Board to carefully read the Herschler reference and reach its own conclusion.

The References Teach Maximum Oral Doses Of MSM Significantly Less Than Claimed

The Answer entirely overlooks the simple fact that the prior art teaches maximum oral dosing regimens substantially different and lower than what is claimed. Claim 1 requires "*orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months.*" The appellant has estimated that the maximum dose disclosed by the prior art, which appears in Salim, is in the range of 33 to 44 mg/kg/day for an unspecified period of time. Appeal Brief, p. 9. The Answer provides nothing substantive to demonstrate disclosure of a higher dose by Salim, because Salim contains absolutely nothing to support such a demonstration. If anything, appellant's estimate of Salim's maximum oral MSM dose is too high. Again, appellant invites the Board to read Salim reach its own fair and

unbiased conclusion. In general, Salim has relatively little to say about oral dosing of MSM and discusses other routes of administration, mainly topical administration, in more detail. Like Herschler, Salim provides no hint that MSM may be effective for lightening skin tone.

The Appeal Brief may have unintentionally *overestimated* the actual maximum oral MSM dose disclosed by Salim. The dose of 33 to 44 mg/kg/day pertains to “the compositions of this invention” and not to pure MSM. Salim, p. 7. The “compositions of the invention” in Salim vary, but all apparently include a mixture of MSM with a sulfur contain amino acid, in various compositions having no more than 20% MSM. See e.g., Salim at claim 1; Example 3 (tables). Assuming a maximum of 20% MSM in an oral composition, the maximum dose of pure MSM disclosed by Salim may be approximately $0.2(44) = 9$ mg/kg/day. Whatever the details, which the Board may ascertain from its own inspection of the reference, Salim certainly does not disclose any oral dose greater than 44 mg/kg/day. More probably, Salim discloses a maximum oral MSM dose of about 9 mg/kg/day compounded with other ingredients.

In addition, Salim discloses no specific oral dosing regimen greater than 6 *hours*, on rats by instillation into the stomach. Example 3. This is much less than the three months disclosed in the application, and clearly not long enough to cause lightening of a person’s natural skin tone.

The reason for administering a therapeutic substance is relevant to patentability. Rapoport v. Dement, 254 F.3d 1053, 1061 (Fed. Cir. 2001). As is undisputed, Salim does not suggest administering MSM to lighten skin tone. In addition, inherent disclosure may not be established by probabilities. Id. at 1063 (finding a prior disclosure

insufficiently specific to anticipate an alternative use of the same compound). Salim likewise merely discloses a different oral dosing regimen that cannot be presumed to include either what is claimed or what would be effective for skin lightening, without a specific disclosure of a known effective regimen.

Lacking prior art for the claimed dosing regimen, the Answer relies on the application to find that one practicing the prior art would have experienced lightening of skin tone. Such a finding is erroneous for reasons explained below, and cannot be justified by any reasonable reading of the application and cited references.

Effective Dose Differs From Any Dose Disclosed By Salim or Herschler

The Answer finds that “[a]ny individual who practices Herschler’s or Salim’s method and takes MSM in such amount will experience the claimed skin color change.” This finding is clearly incorrect and entirely unsupported. The Answer incorrectly asserts that “[a]ccording to applicant’s own disclosure, ‘200-5000 mg of MSM per day’ is sufficient to observe a change in skin color.” Answer at p. 10, citing the application at page 5, bridging paragraph. This assertion mischaracterizes the application disclosure. The application actually discloses at the cited part that “[a] single serving of an ingestible preparation may contain various suitable amounts of MSM, for example, approximately 200-5000 mg per serving.” Clearly, the application is not here discussing a dose, and is merely giving examples of serving sizes that might be administered in any number of servings per day and to patients of various body masses.

The application elsewhere describes effective doses for lightening skin tone. Effective oral doses for a 45 kg female are presented in Table 1 of the application and immediately below Table 1. The lowest effective dose disclosed is 45 mg/kg/day. The

last row of Table I discloses the claimed dose of 133 mg/kg/day, which is the highest disclosed. At the time the application was written, the appellant believed 45 mg/kg/day is the lowest effective dose. Subsequently, the appellant concluded that lower doses may not be sufficiently effective, and amended the claims to define the presently defined dose. The fact remains that the lowest effective dose disclosed in the application, which requires at least a three month period of administration, is much higher than the highest oral dose disclosed by Salim, administered for a much shorter period of merely six hours. Thus, the effective doses claimed or disclosed in the present application differ substantially from any dose expressly or inherently disclosed by Salim or by any other reference.

No Motivation To Increase Oral Dose

The Appeal Brief points out that one of ordinary skill would have had no motivation to discover the claimed dose regimen, because lower doses were already known to be effective for all known cosmetic and therapeutic applications. Appeal Brief, p. 9-10. The Answer rebuts this only by mischaracterizing the present application as teaching lower effective doses than actually disclosed. Answer, p. 10. The falsity of this mischaracterization is demonstrated above. In addition, the Answer finds that the skin tone lightening results would have been expected, relying on another finding that is unsupported and clearly erroneous, as also demonstrated above. The Answer provides no factually-based finding showing any genuine motivation that would have been apparent to one of ordinary skill to discover the claimed dose regimen. The facts remain that: (a) no such motivation has been shown to exist, and (b) the present application discloses novel dosing regimens that are necessary to achieve the

unexpected result of “causing a person to develop a skin tone noticeably lighter than the person’s natural skin tone.” The claims are limited in scope to a novel use of MSM that achieves an unexpected result, and are therefore allowable.

Conclusion

For the reasons stated above and in the Appeal Brief, Appellant respectfully requests the reversal of the rejection of currently pending claims 1, 4-6, 9-11, 13, 15, 17 and 19, and allowance of these claims forthwith.

Respectfully submitted,

Date: May 24, 2011

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